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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,936	11/17/1999	GUST H. BARDY	90980054-1	5202

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EXAMINER
DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,936	BARDY ET AL.	
	Examiner	Art Unit	
	Kristen L Droesch	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7-9 and 16* is/are allowed.

6)☒ Claim(s) *1-6,10-15,17-20,22 and 23* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/17/99* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (5,792,205). Alt et al. shows a method of receiving a cardiac signal form a patient, determining from the signal whether the patient is experiencing atrial fibrillation, identifying an operator of a shock generator, enabling the shock generator if the operator is authorized to operate the shock generator, and shocking the patient with the shock generator in response to a shock command from the operator if the patient is experiencing atrial fibrillation (Col. 4, lines 8-64).

Regarding claim 22, Alt et al. further shows the operator is the patient.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-2, 10, 12-13, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) in view of Morgan et al. (4,610,254). Adams et al. shows an atrial defibrillator (30) comprising a housing (32), shock generator (76) and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal

if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could be implemented with an external defibrillator and associated defibrillator pads (Col. 8, lines 33-34). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the external atrial defibrillator of Adams et al. for the implantable atrial defibrillator of Adams et al. wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. device. Although Adams et al. does not teach that the shock generator (76) is operable to shock the patient via the pads in response to a shock command from the operator, attention is directed to Morgan et al. who teaches an external defibrillator comprising a portable non-implantable housing (12); a pair of defibrillator pads (30, 36), a shock generator (120, 122, 126) disposed in the housing and operable to shock the patient in response to a shock command from an operator (Col. 4, lines 46-48); an analyzer (388) disposed in the housing and operable to receive a cardiac signal from the patient to determine if the patient is experiencing fibrillation and to enable the shock generator (120, 122, 126) if the patient is experiencing fibrillation (Col. 13, line 56-Col. 14, lines 46). Morgan et al. teaches that the device is designed to be used interactively (i.e. the shock generator is enabled dependent on ECG analysis, but the operator must push the shock button to effect the defibrillation shock) so that a properly trained nonmedical operator can safely and effectively operate the device (Col 1, liens 51-53). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the shock generator of the external atrial defibrillator of Adams et al. to make it operable in response to a shock command from an operator as Morgan et

al. teaches in order to allow a properly trained nonmedical operator to safely and effectively use and operate the device.

Regarding claim 2, Morgan et al. shows a control device disposed in the housing, coupled to the shock generator (120, 122, 126) and operable to receive the shock command from the operator to activate the shock generator in response to the shock command. (Col. 9, lines 7-15).

With respect to claims 10 and 18, Adams et al. further shows the analyzer is further operable to determine from the cardiac signal whether atrial fibrillation terminates after the shock generator shocks the patient (Col. 7, liens 44-60).

Regarding claims 12 and 19, Adams et al. further shows the cardiac signal comprises an electrocardiogram that includes an R wave having a rising edge and the analyzer is operable to enable the shock generator during the rising edge of he R wave and to disable the shock generator outside the rising edge (Col. 8, lines 10-22).

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) in view of Brandell. (6,068,651). Adams et al. shows an atrial defibrillator (30) comprising a housing (32), shock generator (76) and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could be implemented with an external defibrillator and associated defibrillator pads (Col. 8, lines 33-34). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the external atrial defibrillator of Adams et al. for the implantable atrial defibrillator of Adams et al. wherein so

doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. device. Although Adams et al. does not teach of a safety device disposed in the housing and operable to prevent the patient from activating the shock generator, attention is directed to Brandell, which teaches a safety device to prevent the patient from activating the shock generator (Col. 7, lines 13-20, Col. 8, liens 10-19). Brandell teaches that the safety device is used to prevent the patient from delivering the atrial defibrillation pulse at a time beyond when it is risky to deliver therapy without first administering anti-coagulants (Col. 2, lines 47-51). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the safety device of Brandell in the atrial defibrillator of Adams et al. in order to prevent the patient from delivering the atrial defibrillation pulse at a time beyond when it is risky to deliver therapy without first administering anti-coagulants.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) in view of Skelton. (6,292,692). Adams et al. shows an atrial defibrillator (30) comprising a housing (32), shock generator (76) and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could be implemented with an external defibrillator and associated defibrillator pads (Col. 8, lines 33-34). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the external atrial defibrillator of Adams et al. for the implantable atrial defibrillator of Adams et al. wherein so

doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. device. Although Adams et al. does not teach of a verification device disposed in the housing and operable to prevent an unauthorized person from activating the shock generator, attention is directed to Skelton which teaches a verification device (44) (Col. 6, lines 44-47). Skelton teaches that the verification device (44) prevents an untrained user to access some of the more advanced treatment modules of the defibrillator such as a manual defibrillation mode (Col. 4, line 65- Col. 5, line 5). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the verification device of Skelton in the atrial defibrillator of Adams et al. in order to prevent an untrained user to access some of the more advanced treatment modules of the defibrillator such as a manual defibrillation mode.

7. Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219) and Morgan et al (4, 610,254) as applied to claims 1 and 13 above and further in view of Ferrari (5,824,033). Adams et al. and Morgan et al. are as explained before. Although Adams et al. and Morgan et al do not teach the defibrillator pads are capable of receiving the cardiac signal, electrode pads capable of both receiving and ECG signals and delivering a defibrillation pulse are well known (See Ferrari). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize defibrillation/sense electrode for the electrodes of Adams et al since they are well known and would have the added benefit of eliminating additional parts.

8. Claims 6, 11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. as (5,207,219) in view of Morgan et al. (4,610,254) and further in view of

Brayshaw (3,663,569). Adams et al. and Morgan et al. are as explained before. Although Adams et al. and Morgan et al. do not specifically teach of an analyzer measuring the duration of R-R intervals and calculating the respective differences, attention is directed to Brayshaw (3,663,569) which teaches an analyzer for detecting atrial fibrillation which measures the R-R interval durations, calculating the respective differences between the lengths of contiguous ones of the R-R intervals, comparing the calculated differences to a difference threshold, and determining that the patient is experiencing atrial fibrillation if one of the calculated difference exceeds the threshold (Col. 4, lines 13-72, Col. 6, lines 9-16). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ atrial fibrillation detection analyzer of Brayshaw for the analyzer of the Adams et al. and Morgan et al. device wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. and Morgan et al device.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,509,925) in view of Adams et al (5,207,219). Adams et al ('925) shows receiving a cardiac signal from a patient, determining from the signal whether the patient is experiencing atrial fibrillation wherein the step of determining comprises determining the patient's heart rate, and determining the patient is not in atrial fibrillation if the heart rate is outside a predetermined range (Col. 2, lines 32-35, Col. 9, lines 34-50). Although Adams et al. ('925) describes the defibrillator (30) as being implantable, Adams et al. ('219) teaches that the implantable defibrillator could be implemented with an external defibrillator and associated defibrillator pads (Col. 8, lines 33-34). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the external atrial defibrillator of Adams et al. ('219) for the

implantable atrial defibrillator of Adams et al. ('925) wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. ('925) device.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (5,207,219). Adams et al. shows an atrial defibrillator (30) comprising a housing (32), shock generator (76) and an analyzer (62) operable to receive a cardiac signal from a patient and to determine from the signal if the patient is experiencing atrial defibrillation and to enable the shock generator (76) if the patient is experiencing atrial fibrillation. Although Adams et al. describes the defibrillator (30) as being implantable, Adams et al. teaches that the invention could be implemented with an external defibrillator and associated defibrillator pads (Col. 8, lines 33-34). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the external atrial defibrillator of Adams et al. for the implantable atrial defibrillator of Adams et al. wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Adams et al. device. Adams et al. discloses the claimed invention except for a multi-phasic waveform. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to modify the output pulse as taught by Adams et al with a multi-phasic waveform, since applicant has not disclosed that this particular waveform provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any waveform such as the waveform taught by Adams et al. for atrial defibrillation.

Allowable Subject Matter

11. Claims 7-9, and 16 are allowed.

Regarding claim 7, the prior art of record fails to teach or suggest a defibrillator including an analyzer which measures the duration of a first group of R-R intervals, calculates the respective differenced between the durations, compares the calculated difference to a difference threshold, repeats the measuring, calculating and comparing for a second group of R-R intervals and determines if a patient is experiencing atrial fibrillation if one of the first group differences *and* one of the second group differences exceed the threshold.

With respect to claims 8 and 16, the prior art of record fails to teach or suggest a defibrillator including an analyzer which measures the duration of a first group of R-R intervals, calculates the respective differenced between the durations, compares the calculated difference to a difference threshold, in combination with calculating a QRS difference between one of the QRS signals of the cardiac signal and a QRS signal stored in the analyzers memory, and comparing the calculated QRS difference to a QRS threshold.

Regarding claim 9, the prior art of record fails to teach or suggest a defibrillator including an analyzer which measures the duration of a first group of R-R intervals, calculates the respective differenced between the durations, compares the calculated difference to a difference threshold, in combination with determining whether the patient's heart rate is within a predetermined range of heart rates and determines if a patient is experiencing atrial fibrillation if one of the differences exceeds the threshold and the heart rate is within the predetermined range.

12. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and

any intervening claims. The prior art of record fails to teach or suggest a method including enabling the shock generator if the operator is authorized to operate the shock generator in combination with disabling the shock generator if operator is identified as the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld
December 31, 2001

KENNEDY SCHAETZLE
PRIMARY EXAMINER
12/31/01